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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul R. Roberts

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EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,934	Applicant(s) ROBERTS, PAUL R.	
	Examiner EMILY M. LLOYD	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's 22 January 2009 amendment. Claims 11-19 and 21-29 are pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the external closure for the filling lumen; collapsed condition of the expandable device; cage having a plurality of arcuate arms extending between opposite poles; external telescopic connector; inflatable device; orientation means of the expandable device; lumen adapted to receive a stiff curved guide member; position sensing apparatus for the tip of the ablation tool; and the valve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 19, it is unclear if the inflation lumen and external closure are the same as those in claim 11 or instead are an additional inflation lumen and external closure. For the purpose of examination, the Examiner has interpreted these elements as being the same as those of claim 11.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-15, 18, 19, 21-23 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5617876 (van Duyl).

Regarding claim 11, Van Duyl discloses an apparatus for detecting the location of electrical activity in the wall of a human bladder (Figures 2, 4, 6C and 6D), comprising: a detector adapted to be introduced into the bladder via the urethra, and having a connector to the exterior (electrodes 9 with insulated leads 17 Figures 2 and 4); a filling lumen adapted to permit passage of a sterile fluid from the exterior through an open end of the filling lumen into the bladder for distending the bladder (catheter 1 Figures 2 and 4); and an external closure for the filling lumen, the closure being effective when closed to maintain the bladder in a distended state, and being effective when released to drain the bladder (Column 7 lines 45-53, Column 18 lines 8-12, Column 8 lines 41-45, Column 12 lines 19-21, and Column 16 lines 10-19).

Regarding claims 12-15, 18, 19, 21-23 and 29 Van Duyl discloses the apparatus according to claim 11 wherein the detector comprises an expandable device adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder (elastic balloon 3 Figure 2, also Column 7 lines 15-20); wherein said expandable device has a plurality of detection sites thereon (electrodes 9 Figure 2); wherein said detection sites are uniformly distributed on the surface thereof (Figures 6C and 6D); wherein said expandable device resembles a sphere in the expanded state (Figures 2, 6C and 6D); wherein the expandable device comprises an inflatable device (elastic balloon 3 Figure 2); wherein said device includes an inflation lumen for inflating the inflatable device, the inflation lumen having an external closure (catheter 1 Figures 2 and 4; Column 7 lines 45-53, Column 18 lines 8-12, Column 8 lines 41-45, Column 12 lines 19-21, and Column 16 lines 10-19); further comprising multiple lumens (lumen of

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catheter 1 and liquid supply line 25 Figure 4, as well as catheter/lumen for draining urine Column 14 lines 52-54); comprising an array of detection sites on the detector adapted to detect electrical activity in the wall of the bladder whereby the location of said electrical activity can be determined (electrodes 9 Figures 2, 4, 6C and 6D, also Column 8 lines 7-11 and Column 9 lines 30-35, as well the entire document); wherein said detection sites are uniformly distributed (Figures 6C and 6D); and wherein the external closure for the filling lumen comprises a valve (syringe Column 12 lines 19-21).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as applied to claims 11-15, 18, 19, 21-23 and 29 above.

Regarding claim 25, van Duyl discloses a lumen (catheter 1 Figures 2 and 4). Van Duyl do not expressly disclose the use of the lumen to receive a stiff curved guide member for steering of the expandable device. However, any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art for guiding and placing catheters.

11. Claims 16, 17 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as applied to claims 11-15, 18, 19, 21-23 and 29 above, and further in view of United States Patent 5662108 (Budd et al.).

Regarding claims 16, 17 and 24-28, van Duyl discloses the claimed invention, except for the expandable device comprising a cage having a plurality of arcuate arms extending between opposite poles; an external telescopic connector whereby relative telescoping movement causes the device to expand and contract on demand; orientation means whereby the orientation of the expandable device in the bladder may be determined from outside the bladder; a lumen adapted to receive a stiff curved guide member for steering of the expandable device; an ablation tool adapted for insertion through the urethra and operable to ablate the internal surface of the bladder wall; the

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tip of said tool is detectable by a position sensing apparatus; and the tip of said tool is adapted to be electrically active and wherein said apparatus is adapted to detect said activity.

Budd et al. teach an expandable device comprising a cage (Budd et al. basket catheter 80 Figure 4) having a plurality of arcuate arms (Budd et al. limb 82 Figure 4) extending between opposite poles (Budd et al. proximal and distal ends of central shaft 86 Figure 4); an external telescopic connector whereby relative telescoping movement causes the device to expand and contract on demand (Budd et al. Column 8 lines 64-67; the device inherently can contract as it is also removable from the body); orientation means whereby the orientation of an expandable device in the bladder may be determined from outside the bladder (Budd et al. Column 11 line 44 – Column 12 line 7); a lumen adapted to receive a stiff curved guide member for steering of the expandable device (Budd et al. a catheter such as balloon catheter 94 inherently has a lumen; any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art); an ablation tool (Budd et al. therapy catheter 18 Figure 3) adapted for insertion through the urethra and operable to ablate (Budd et al. delivery electrode 60 Figure 3 and Column 5 lines 17-18) the internal surface of the bladder wall; the tip of said tool (Budd et al. delivery electrode 60 Figure 16) is detectable by a position sensing apparatus (Budd et al. locator electrode 68 Figure 16); and the tip of said tool is adapted to be electrically active (Budd et al. delivery electrode 60 Figure 3) and wherein said apparatus is adapted to detect said activity (Budd et al. Column 4 lines 42-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the previously cited elements of Budd et al. with the invention of van Duyl as a substitution of equivalents known in the art for providing an array of electrodes inside the body (the cage having a plurality of arcuate arms extending between opposite poles is an equivalent known in the art for a balloon with electrodes, each providing an array of electrodes that can be closed for insertion into the body and opened for use upon entry to the body, see Budd et al. Figures 3 and 4 and MPEP 2144.06 II Substituting Equivalents Known For The Same Purpose). It further would have been obvious to combine the previously cited elements of Budd et al. with the invention of van Duyl to further provide assurance that the electrodes of Figures 2 and 4 of van Duyl are facing in the correct direction (Budd et al.'s orientation means would confirm van Duyl's positioning Column 14 lines 45-48); and to provide for treatment of any abnormalities found (the ablation tool of Budd et al., with the tip being detectable by a position sensing apparatus and adapted to be electrically active would provide for treating any abnormalities found by the invention of van Duyl).

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Duyl as applied to claims 11-15, 18, 19, 21-23 and 29 above, and further in view of United States Patent 6152920 (Thompson et al.).

Regarding claim 25, van Duyl disclose a lumen (catheter 1 Figures 2 and 4). Van Duyl do not expressly disclose the use of the lumen to receive a stiff curved guide member for steering of the expandable device. Thompson et al. teach the use of a lumen (Column 9 lines 20-21 "guidewire 46 passes through a lumen in the shaft 14") to

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receive a stiff curved guide member for steering of the expandable device (guidewire 46 Figure 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the use of a lumen to receive a stiff curved guide member for steering of the expandable device as taught by Thompson et al. with the invention of van Duyl to provide for directing and/or anchoring the invention of van Duyl as it is positioned in the bladder (Thompson et al. Column 9 lines 16-28).

Response to Amendment

13. The declaration under 37 CFR 1.132 filed 22 January 2009 is sufficient to overcome the rejection of claims 11-19 and 21-29 based upon Streng et al. as modified by Budd et al. applied under 35 USC 103.

Response to Arguments

14. Applicant's arguments with respect to claims 11-19 and 21-29 have been considered but are moot in view of the new ground(s) of rejection.

15. In response to applicant's argument that Budd et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Budd et al. measures electrical activity of a liquid filled body part (the heart), which is similar to a liquid filled urinary bladder. One of ordinary skill in the art, when trying to measure electrical activity of a liquid filled or hollow body part, would turn to

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measurement techniques and devices for other similar body parts, such as the heart, uterus, and stomach.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

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/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736